UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. DR. REDDY'S LABORATORIES INC., et al., Defendants.	Civil Action No. 11-2317 (JAP) (lead case) 11-4275 (JAP) 11-6348 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E, Inc. and Pozen, Inc. ("Astra" or "Plaintiffs") bring these Hatch-Waxman patent infringement actions against Defendants Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories Ltd (together, "Dr. Reddy's"), Lupin Ltd., Lupin Pharmaceuticals Inc. (together, "Lupin"), Anchen Pharmaceuticals, Inc. ("Anchen") alleging infringement of U.S. Patent No. 6,926,907 (the " '907 patent"), No. 6,369,085 (the " '085 patent"), No. 7,411,070 (the " '070 patent"), No. 7,745,466 (the " '466 patent"), No. 5,714,504 (the " '504 patent") and 6,875,872 (the " '872 patent"). Presently before the Court is the parties' request for claim construction. The Court has held a *Markman* hearing and construes the disputed claim terms as set forth below.

I. BACKGROUND

Astra's pharmaceutical product Vimovo is a combination drug that contains the active ingredients naproxen, which is a non-steroidal anti-inflammatory drug ("NSAID"), and

esomeprazole magnesium trihydrate, which is a proton pump inhibitor ("PPI"). Vimovo is used to treat the symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis. The esomeprazole magnesium trihydrate in Vimovo is the same active ingredient in Astra's drug product Nexium, an acid inhibitor used to treat gastrointestinal disorders. With the combination of these two drug products, patients taking Vimovo have a decreased risk of developing NSAID-associated gastric ulcers.

There are six patents-in-suit. The '085 patent, the '070 patent and the '466 patent relate to esomeprazole magnesium trihydrate. The relevant claims of the '907 patent relate to a unit dosage form which contains a combination of an NSAID and an acid inhibitor. The '504 and '872 patents relate to optically pure compositions of certain omeprazole salts. Four of the patents, specifically, the'504 patent, '872 patent, '085 patent and '070 patent, have been the subject of other actions before this court involving the drug Nexium and, consequently, the Court has previously considered and ruled upon the meaning of certain of claim terms at issue in this case. *See AstraZeneca AB v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 05-5553 (JAP) (the "Nexium action"). In addition to the claim terms being addressed by this Court for the first time in the instant actions, Defendants have asked the Court to reconsider some of its earlier rulings with regard to some of the disputed claim terms.

II. LEGAL STANDARD

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal

quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("we look to the words of the claims themselves ... to define the scope of the patented invention"). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), therefore, it is "[t]he duty of the trial judge ... to determine the meaning of the claims at issue," *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312–13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of "the words of the claims

themselves, the remainder of the specification, [and] the prosecution history," *id.* at 1314, and extrinsic evidence "concerning relevant scientific principles, the meaning of technical terms, and the state of the art," *id.*

When considering the intrinsic evidence, the court's focus must begin and remain on the language of the claims, "for it is that language that the patentee chose to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.' " *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001) (quoting 35 U.S.C. § 112, ¶ 2). The specification is often the best guide to the meaning of a disputed term. *Honeywell Int'l v. ITT Indus.*, 452 F.3d 1312, 1318 (Fed.Cir.2006). It is improper, however, to import limitations from the specification into the claims. *Seachange Int'l v. C–COR Inc.*, 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may also consider as intrinsic evidence a patent's prosecution history, which is evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the

court, ... it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Extrinsic evidence may never be used to contradict intrinsic evidence. *Id.* at 1322–23.

III. CONSTRUCTION OF THE DISPUTED CLAIM TERMS

The '907 Patent

The '907 patent is

> directed to a drug dosage forms that release an agent that raises the pH of a patent's gastrointestinal tract, followed by a non-steroidal anti-inflammatory drug. The dosage form is designed so that the NSAID is not released until the intragastric pH has been raised to a safe level. The invention also encompasses methods of treating patients by administering this coordinated release, gastroprotective, antiarthritic/analgesic combination unit dosage form to achieve pain and symptom relief with a reduced risk of developing gastrointestional damage such as ulcers, erosions and hemorrhages.

'907 Patent, Abstract. All of the disputed terms of the '907 patent are found in claim 1. This claim is set forth below, and discussion of the disputed claim language follows.

Claim 1 of the '907 patent reads:

> A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:
>
> (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
>
> (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms; and wherein said unit dosage form provides for coordinated release such that:
>
> i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;

> ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

'907 patent, claim 1.

The parties dispute the construction of the following portions of the claim:

1. "*an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms*"

Plaintiffs contend that this term should be construed as "an acid inhibitor present in an amount capable of raising the gastric pH of said patient to at least 3.5 upon the administration of one or more single entities for drug administration over a period of time." Defendants argue that this term means "an acid inhibitor present in the unit dosage form in an amount effective to raise gastric pH to at least 3.5 at the time the unit dosage form is administered." The key difference in the parties' constructions centers on whether the acid inhibitor contained in the unit dosage form must be in an amount sufficient to raise gastric pH to 3.5 upon administration of a single dose. As can be seen from the proposed constructions, Plaintiffs contend that the disputed claim language encompasses pharmaceutical compositions that may require multiple administrations before the acid inhibitor is effective to raise the gastric pH to the desired level, while Defendants contend that the acid inhibitor must obtain the desired effectiveness in a single dose. Contrary to Defendants' arguments, the Court finds that the relevant evidence supports the conclusion that the claim language encompasses an acid inhibitor that may require more than one dose to achieve the desired effectiveness.

Significantly, the claim language itself states that achieving the goal of raising gastric pH to 3.5 may occur upon administration of "one or more" unit dosage forms. There is no

language limiting the "one or more" unit dosage forms to a single administration. Defendants' construction, while focusing on the words "upon the administration," improperly reads out the "or more" portion of the claim language. *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (noting courts must construe claims with an eye toward giving effect to all the terms in the claim). The "or more" language appears to be specifically designed takes into account the fact that, as acknowledged in the patent, the effect of certain types of acid inhibitors "may be delayed for several hours and may not take full effect for several days." '907 patent, col.1, lines 62–63. Overall, taking into account all of the relevant evidence cited by the parties and, in particular, the language of the patent itself, the Court finds that the evidence does not support Defendants' construction.

Plaintiffs' proposed construction, while a more accurate construction than Defendants', seems to unnecessarily complicate the issue by swapping certain words in the claim with various synonyms. For example, Plaintiffs' construction swaps "effective to raise" with "capable of raising" and "administration of one or more of said unit dosage forms" with "administration of one or more single entities." The Court, however, sees no reason to depart from the clear claim language, and will adopt a construction similar to that proposed by Plaintiffs but which modifies the claim language less so than Plaintiffs' proposed construction. The Court finds that a person of skill in the art would understand the term "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms" to mean "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms over a period of time" and, consequently, construes the term accordingly.

2. "*wherein said unit dosage form provides for coordinated release*"

Plaintiffs argue that the Court should construe this term to mean "wherein the single entity for drug administration provides for the sequential release of acid inhibitor followed by NSAID." Defendants, on the other hand, contend that the proper construction is "release of the NSAID in the unit dosage form is prevented until the acid inhibitor in the unit dosage form increases gastric pH to at least 3.5." The relevant evidence supports Plaintiffs' construction.

As an initial matter, the specification itself defines "coordinated release" as being sequential, namely, the release of an acid inhibitor followed by the release of an NSAID. Specifically, the specification states that "[a]ll of the dosage forms are designed for oral delivery and provide for the coordinated release of therapeutic agents, i.e., for the sequential release of acid inhibitor followed by analgesic." '907 patent, col. 5, lines 16-19. Further, the claim itself describes a sequential release -- the acid inhibitor is first released and the release of the NSAID is delayed until the pH in the "surrounding medium," is 3.5 or higher. This is also described in the specification, which indicates that the dosage form "provides for coordinated release . . . i.e., the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the GI tract has risen." '907 patent, col 3. line 63 to col 4. line 2. During prosecution, the applicant similarly characterized the claimed release as sequential in nature, *i.e.*, the release of the acid inhibitor followed later by the NSAID release. *See*, *e.g.*, Andersen Decl. Ex. 5. Overall, the claim language, the specification, and the prosecution history describe a sequential release of drugs, the first of which is the release of the acid inhibitor, which is then followed by the release of the NSAID once the pH of the surrounding environment reaches the appropriate pH.

The Court, consequently, finds Plaintiffs' construction to be more consistent with the intrinsic evidence and rejects Defendants' proposed construction. Defendants' construction reads the disputed claim language too narrowly, as the "surrounding medium" is not limited to the stomach as Defendants' construction would require. The specification explains that where gastric pH has not reached the requisite pH the NSAID would not release until it "reaches an environment where the pH is above about 4," which would be in the small intestine. '907 patent, col. 14, lines 59–65; *see also,* col. 13, lines 12–18. Having considered all of the relevant evidence, the Court concludes that a person of skill in the art would understand the disputed term to mean "wherein said unit dosage form provides for coordinated release" to mean "wherein the single entity for drug administration provides for the sequential release of acid inhibitor followed by NSAID."

3. "*a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher*"

The parties' dispute over this term relates to the manner in which the specified coating controls the release of the NSAID. Defendants seek a construction that specifies that the means by which the coating controls the release includes both by time and by pH. They propose the following construction: "a coating that, upon ingestion of said unit dosage form by said patient, controls the release of NSAID by time or pH and thereby prevents the release of essentially any NSAID form said dosage form unless the pH of the surrounding medium is 3.5 or higher." Plaintiffs, on the other hand, contend that the plain and ordinary meaning of the phrase should apply, and, further, that the plain and ordinary meaning requires that the coating control the release of the NSAID by pH only and not by time.

The Court agrees with Plaintiffs, and concludes that the plain and ordinary meaning of this phrase, which states that the form of control for NSAID release is pH, should apply. The language of the claim itself is clear. The coating prevents the release of the NSAID "unless" the pH of the surrounding medium is 3.5. The term "unless" as it is used here is conditional, not temporal. There is nothing in the claim language itself directed toward controlling the release of the NSAID by time. The Court's conclusion is further supported by the fact that the prosecution history shows that during prosecution the applicant replaced "said NSAID is not released *until* the gastric pH of said patient is 3.5 or higher" with the language that states NSAID release is prevented "*unless* the pH of the surrounding medium is 3.5 or higher". *See* Andersen Decl. Ex. 3 (emphasis added).

Defendants' have not convinced the Court that departure from the plain language of the claim is appropriate and their arguments in support of their proposed construction are unavailing. While it is true that the specification describes two alternative types of coatings, namely, one that controls release by pH and one that controls by time, the time release coating is covered elsewhere in the claims. *See, e.g.*, claim 37; *see also Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1337 (Fed. Cir. 2007) ("A patentee may draft different claims to cover different embodiments."). Defendants also point to claims 19 and 20 -- which depend on claim 1 and are directed to a "barrier coating" that dissolves at a certain rate -- in arguing that that claim 1 must encompass time-dependent coating. In doing so, however, Defendants ignore that claims 19 and 20 refer to a different coating than claim 1. Consequently, the Court rejects Defendants proposed construction and finds that the plain and ordinary meaning of the disputed phrase shall apply. Under the plain and ordinary meaning, the coating controls the release of the NSAID by pH only.

4. "*enteric coating*"

The term enteric coating is not expressly defined in the patent. It appears that the parties generally agree that an enteric coating is a delayed-release coating that does not dissolve in the stomach but, rather, dissolves after passing through the stomach to permit release of a drug further down in the digestive tract. Indeed, this is consistent with the specification of the '907 patent, which makes clear that an enteric coating delays release of a drug until after it has passed through the stomach. '907 patent, col 1 line 64 to col. 2 line 2 ("[T]his class of drugs is enteric coated to avoid destruction by stomach acid."); col. 9 lines 50–57 ("The function of the enteric coat is to delay the release of naproxen . . . . The coating does not dissolve in the harshly acidic pH of the unprotected stomach.").

Where the parties' constructions diverge with regard to this term is related to the breadth of the construction. Plaintiffs propose that the term "enteric coating" be construed more generally to mean "a delayed release coating." Defendants seek a more specific construction of the term, *i.e.*, "a coating that controls the release of an active agent from a unit dosage form by pH." In support of their construction, Plaintiffs argue that the term "enteric" would be understood by one that is skilled in the art as a coating that delays dissolution of the coating and release of the drug further in the digestive tract, but it does not limit the manner in which the drug release is delayed. Defendants counter that persons skilled in the art generally understand an "enteric coating" to be pH dependent.

There is limited intrinsic evidence that sheds light on the question of the proper construction of the term. Plaintiffs point out that the background section of the specification at one point mentions a "pH sensitive enteric coating," which Plaintiffs claim would be redundant if the Defendants' construction were correct. This weighs somewhat in favor of

Plaintiffs' construction, but alone it is not sufficient and, therefore, it is appropriate to turn to extrinsic evidence. Not surprisingly, the parties offer conflicting expert opinions. Plaintiffs' expert opines that a person of ordinary skill in the art would understand the term "enteric coating" to mean a delayed release coating, one typically used to delay release of the drug until it reaches the intestines. Williams Decl. ¶ 42-46. Plaintiffs' expert bases his opinion in part on the FDA's *Guidance for Industry SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation* (September 1997), which defines "enteric coated" as "[i]ntended to delay the release of the drug (or drugs) until the dosage form has passed through the stomach. Enteric coated products are delayed release dosage forms." Williams Decl. Ex. C. Plaintiffs' expert also relies upon a textbook on pharmaceutical dosage forms which describe enteric coatings that can be either pH-dependent, enzyme-dependent or time-dependent. Defendants' expert takes a contrary view, and points to certain scientific literature describing pH-dependent enteric coatings.

Considering the relevant extrinsic evidence, the Court concludes that one skilled in the relevant art would understand the term "enteric coating" to be a delayed release coating. While the evidence shows that an enteric coating is commonly and perhaps frequently pH-dependent, the evidence shows that other types of enteric coatings are utilized in the field. There is nothing in the patent or otherwise that directs a construction that limits the term "enteric coating" in claim 1 of the '907 patent to strictly a pH-dependent form. The Court, therefore, will construe the term consistent with Plaintiffs' proposed construction.

5. "*at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5*"

The parties both contend that this phrase should be given its plain and ordinary meaning but, unfortunately, disagree on what the plain and ordinary meaning is. Plaintiffs argue that this phrase means "at least a portion of said proton pump inhibitor is immediately released." Defendants contend that this phrase means "at least some amount of acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5." Defendants' explain that their construction, however, incorporates their proposed construction of "enteric coating," which requires the enteric coating specifically to be a pH dependent coating. Thus, under Defendants' proposed construction of the instant phrase, the claim would exclude only the use of a pH-dependent coating on a portion of the acid inhibitor, but not the use of other delayed release coatings, such as those coatings that are time-dependent. However, the Court rejected of Defendants' proposed construction for "enteric coating," finding that the term "enteric coating" was not limited to pH-dependent coatings only. The Court, therefore, rejects Defendants' proposed construction here.

The claims themselves as well as the specification make clear that the acid inhibitor of the invention releases "immediately" upon ingestion due to the absence of a delayed release coating. *See, e.g.*, '907 patent, col. 8, lines 47-49 (stating that the acid inhibitor in Example 1 is "released from the dosage form immediately after administration"); col. 9, lines 60-62 (same for Example 2); *see also* Example 3 and Example 4. This is consistent with the "plain and ordinary" meaning of the term advanced by Plaintiffs. Keeping its construction as close

as the claim language as possible, the Court construes this term as follows: "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is immediately released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5."

The '085 patent, '070 patent, '466 patent

As stated earlier, Vimovo contains an NSAID, naproxen, and a proton pump inhibitor, the trihydrate form of esomeprazole magnesium. The '085 and '070 patents relate to esomeprazole magnesium trihydrate; and the '466 patent relates to the combination of esomeprazole magnesium trihydrate and a second active ingredient selected from a specified group. These three patents have the same inventors and the same specification, but their claims differ. The '085 patent is limited to a specific form of "the magnesium salt of S-omeprazole trihydrate" characterized by certain x-ray diffraction "d-values." '085 patent, col.10 lines 5–34. The '070 patent later issued claiming a form of esomeprazole magnesium trihydrate and certain preparation processes. The '466 patent claims pharmaceutical compositions and methods of treatment comprising esomeprazole magnesium trihydrate and a second active ingredient.

1. "*magnesium salt of S-omeprazole trihydrate*"

This term appears in the claims of the '085 patent (claims 1-5, 7-14, 16), '070 patent (claim 1-4), '466 patent (claims 1-4, 12). Plaintiffs offer the following proposed construction: "magnesium salt of S-omeprazole having approximately three molecules of bound water per molecule of S-omeprazole magnesium."[1] Defendants proposed construction is as follows: "a trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per

[1] This is not the same proposed construction that appears in the parties' Joint Claim Construction and Prehearing Statement. Plaintiffs submitted this "streamlined" proposed construction shortly before the *Markman* hearing.

molecule of magnesium salt of S-omeprazole in a unit cell of the crystal lattice that is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole including S-omeprazole dihydrate and amorphous forms."

This disputed term appears in the asserted claims of the three trihydrate patents. Claim 1 of the '070 patent, which reads in its entirety, "[t]he magnesium salt of S-omeprazole trihydrate," is a simple compound claim, while the other asserted claims address preferred embodiments and processes and pharmaceutical compositions. The Court finds that it is clear from a comparison of the claims themselves that the term ""[t]he magnesium salt of S-omeprazole trihydrate" is intended to have a broad construction. Having considered the relevant evidence, the Court simply finds no basis to import the limitations sought by Defendants into the claim language.

The Court, however, agrees with Defendants that Plaintiffs' construction is flawed to the extent that it seeks to define the trihydrate as having "approximately" three molecules of water. This simply is not consistent with the plain and ordinary meaning of the term trihydrate. Consequently, the Court shall construe "magnesium salt of S-omeprazole trihydrate" as "a trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole."

2. "*characterized by the following major peaks in its X-ray diffractogram*"

This term appears in the '085 patent (claims 1-4, 12) and the '466 patent (claims 3, 11). Plaintiffs contend this phrase means "identifiable by reference to an X-ray diffractogram that includes the major peaks below." Defendants, on the other hand, offer this proposed construction: "having all of the referenced major peaks in its X-ray diffractogram."

Claim 1 of the '085 patent reads: "The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram:"

d-value / Å	Relative Intensity
2.67	m
2.79	m
3.27	m
3.52	s
3.82	s
3.96	vs
4.14	m
5.2	m
5.6	m
6.7	vs
6.9	s
8.3	w
16.6	vs

The numbers in the left column indicate a position on the x-axis of a peak in an X-ray diffractogram of the material in question and the letters in the right column indicate a relative intensity of the corresponding peak.[2] The difference between the parties' proposed construction centers on whether the S-omeprazole trihydrate at issue must have all of the referenced peaks without exception.

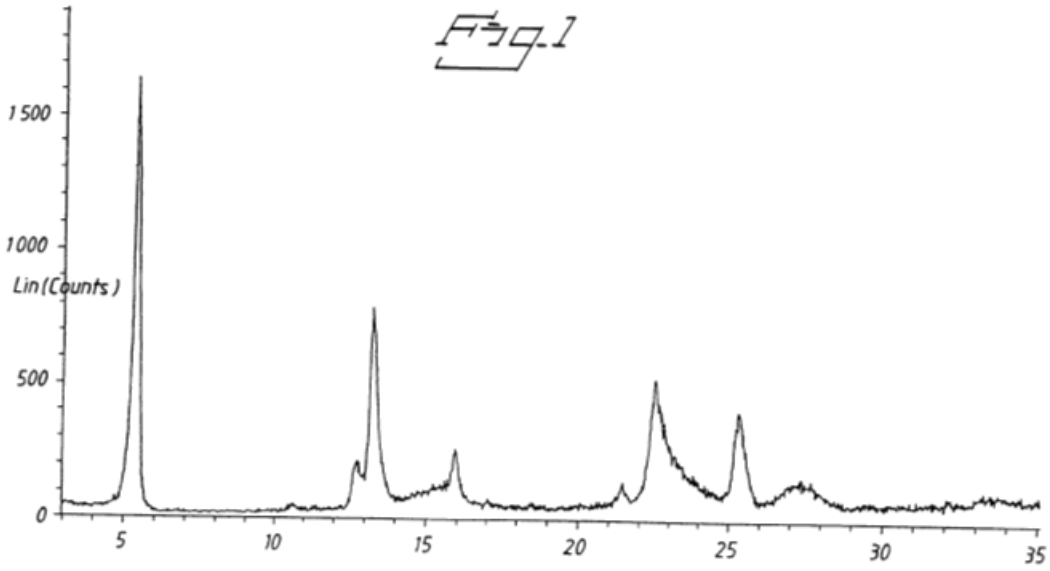
The Court concludes that Defendants' construction, which would require an exact match, is too rigid. The claim language requires only that the S-omeprazole trihydrate be "characterized" by the peaks in the table, not necessarily that it have a perfect one-to-one relationship. Even Defendants' expert concedes that although the X-ray diffraction of a compound will have the same "general appearance," the positions of the peaks may differ somewhat because of slight experimental errors. Plaintiffs' construction accounts for such differences, while Defendants' would not. Consequently, the Court will construe

[2] As noted in the '085 patent, the definitions of the abbreviations used in the right column are as follows: vs (very strong), s (strong), m (medium), w (weak), vw (very weak).

"characterized by the following major peaks in its X-ray diffractogram" to mean "identifiable by reference to an X-ray diffractogram that includes the major peaks below."

3. "*represented by FIG. 1*"

This term appears in the '070 patent (claims 2, 4) and the '466 patent (claims 2, 10). The claim language refers to the following graph designated as Figure 1 in these patents:



The diffractogram of Figure 1 shows position (x axis) plotted against intensity (y axis), obtained when a powder sample is irradiated with X-rays at various angles indicated by the values on the x axis.

According to Plaintiffs, the disputed term "represented by FIG. 1" means "represented by Figure 1 of the '070 patent (or '466 patent)." Defendants contend that this term means "having an X-ray diffractogram the same as FIG. 1." As with the previously discussed term "characterized by the following major peaks in its X-ray diffractogram", here again difference the parties' proposed construction boils down to whether "represented by FIG. 1" requires that the S-omeprazole trihydrate at issue must have an X-ray diffractogram that is perfectly

identical to Figure 1. For reasons similar to those with respect to the previous term, the Court again finds Defendants' construction too rigid. Accordingly, the term "represented by FIG. 1" shall be construed consistent with Plaintiffs' proposed construction, namely, "represented by Figure 1 of the '070 patent (or '466 patent)."

'504 and '872 Patents

The '872 patent claims the magnesium salts of the (–)-enantiomer of omeprazole exhibiting high or very high optical purities of "at least about": 94% (claim 1), 98.4% (claim 4), 99.8% (claim 7), and 99.9% (claim 10), measured by enantiomeric excess. Claims 5, 8, and 11 are parallel to claims 4, 7, and 10, only the "about" language is removed. Claims 3, 6, and 9 limit the independent claims to those containing esomeprazole magnesium compounds "in crystalline form."

The '504 patent claims pharmaceutical formulations (and treatment methods) comprising solid, chemically pure alkaline salts of the (–)-enantiomer of omeprazole and a pharmaceutically acceptable carrier. This claim is further limited to "optically pure" alkaline salts of (–)-omeprazole (claim 2); specific alkaline salts, such as magnesium or sodium (claims 3 and 5); and salts in a "substantially crystalline form" (claim 4). Claims 6 and 10 are directed to methods of using the claimed formulation.

1. "*(-)-enantiomer of 5-metholy-2[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole*" and "*optically pure*"

These terms appear in the claims of the '504 patent. The Court previously construed "(–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5- dimethyl-2-pyridinyl)met-hyl]sulfinyl]-1H-benzimidazole" (claims 1-6 and 10) in the Nexium action to mean "(–)-omeprazole of high optical purity, also referred to as (S)-omeprazole, the (S)-enantiomer of omeprazole"

wherein "high optical purity" means at least 94% enantiomeric excess and, when modified by "optically pure," (claim 2) in at least 98% enantiomeric excess. *Dr. Reddy's*, 2010 WL 1981790 at *6-8. Plaintiffs ask the Court to adopt its previous construction here, while Defendants urge the Court to adopt an alternative construction that the Court previously rejected. The Court has carefully considered Defendants' arguments, but finds no basis to alter its earlier construction. For the same reasons in its decision in the Nexium action, the Court shall construe "(–)-enantiomer of 5-methoxy-2[[(4-methoxy-3,5- dimethyl-2-pyridinyl)met-hyl]sulfinyl]-1H-benzimidazole" to mean "(–)-omeprazole of high optical purity, also referred to as (S)-omeprazole, the (S)-enantiomer of omeprazole" wherein "high optical purity" means at least 94% enantiomeric excess and, when modified by "optically pure," (claim 2) in at least 98% enantiomeric excess.

2. "*in substantially crystalline form*"

This term appears in claim 4 of the '504 patent. The Court previously construed this term in the Nexium action to mean "sufficient crystallinity present to permit further optical purification of the enantiomer if required." *Dr. Reddy's*, 2010 WL 1981790 at *8. Plaintiffs ask the Court to adopt its previous construction here, while Defendants urge the Court to adopt an alternative construction based upon arguments that the Court previously rejected. The Court has carefully considered Defendants' arguments, but finds no basis to alter its earlier construction. For the same reasons in its decision in the Nexium action, the Court shall construe "in substantially crystalline form" to mean "sufficient crystallinity present to permit further optical purification of the enantiomer if required."

3. "*in crystalline form*"

This term appears in claims 3, 6 and 9 of the '872 patent. The Court previously construed this term in the Nexium action to mean "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species." *Dr. Reddy's*, 2010 WL 1981790 at *3. Plaintiffs ask the Court to adopt its previous construction here, while Defendants urge the Court to adopt an alternative construction that the Court previously rejected. The Court has carefully considered Defendants' arguments, but finds no basis to alter its earlier construction. For the same reasons in its decision in the Nexium action, the Court shall construe "in crystalline form" to mean "at least some of the magnesium salt of esomeprazole present is in a solid with a repeating pattern of atoms or molecules of the constituent chemical species."

IV. CONCLUSION

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: April 30, 2013